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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,155	WANG ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5-4-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 1, 3, 4 and 11-13, and SEQ ID No. 160, in the reply filed on 3-24-06 is acknowledged. The traversal is on the ground(s) that the polynucleotides of SEQ ID Nos. 128, 129, 132, 160, 167, 168, 254, 358, 370-375 and 431 are not derived from different genes, and they are related to each other because they correspond to different regions of or the complete sequence of the same lung tumor antigen, L762P. Applicants argue that there is no undue burden to search all the related sequences. This is not found persuasive because those sequences are either the variant of SEQ ID No. 160, such as SEQ ID Nos. 167 and 168, or they are just fragments of SEQ ID No. 160, such as SEQ ID Nos. 128, 129, 132, and 370-375, or they encode fusion proteins. They have different nucleotide sequences and have different biological function. For example, a fragment of SEQ ID No. 160 can be used as a primer, a probe or an antisense sequence to target a particular region of SEQ ID No. 160. Therefore, they require separate search and search for all those sequences would impose serious burden on examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2, 5-10 and 14-17, and SEQ ID Nos. 128, 129, 132, 167, 168, 254, 358, 370-375 and 431 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3-24-06.

Applicants amendment filed 3-24-06 has been entered. Claims 2, 5-10 and 14-17 have been canceled. Claims 1, 3, 4 and 11-13 are pending. Claims 1, 3, 4 and 11-13 and SEQ ID No. 160 are under consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3, 4 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "at least 20 contiguous residues of a sequence" in (c) of claim 1 is vague and renders the claim indefinite. The term "residue" usually is used to refer to amino acid residue, however, the sequence of SEQ ID No. 160 is a DNA sequence. It is unclear whether the phrase "at least 20 contiguous residues of a sequence" refers to amino acid residues or nucleotide sequence. Claims 3, 4 and 11-13 depend from claim 1 but fail to clarify the indefiniteness.

5. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: whether the polynucleotide is expressed and sufficient amount of gene product is produced so as to stimulate an immune response in a patient, and whether the polynucleotide that is administered to a patient stimulates an immune response in said patient.

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MEP. § 2172.01. The omitted steps are: whether the polynucleotide is expressed and sufficient amount of gene product is produced so as to treat a lung cancer in a patient.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 4 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on an isolated polynucleotide comprising a sequence of SEQ ID No. 160, complement of SEQ ID No. 160, a sequence consisting of at least 20 contiguous nucleotides of SEQ ID No. 160, a sequence that hybridizes to SEQ ID No. 160 under highly stringent condition, a sequence having at least 75% or 90% identity to SEQ ID No. 160, degenerate variants of SEQ ID No. 160, and a composition comprising said polynucleotide.

The specification only discloses a polynucleotide sequence of SEQ ID No. 160 and the amino acid sequence (SEQ ID No. 161) encoded by SEQ ID No. 160. The claims encompass any polynucleotide comprising SEQ ID No. 160, any polynucleotide that has at least 20 contiguous nucleotides of SEQ ID No. 160, hybridizes to SEQ ID No. 160 under highly stringent condition, has at least 75% or 90% identity to SEQ ID No. 160, and degenerate variants of SEQ ID No. 161.

The claims read on adding unknown nucleotide sequence at 5', 3' ends and/or within the nucleotide sequence of SEQ ID No. 160, or deleting or substituting the nucleotide sequence of

SEQ ID No. 160. Twenty-five% or ten% difference from the sequence of SEQ ID No. 160 (3951 nucleotides) accounts to about 990 nucleotides and 395 nucleotides, respectively. The resulting polynucleotide sequence differs dramatically from the sequence of SEQ ID No. 160, and the polypeptide encoded by said polynucleotide sequence also could differ dramatically or totally different from the sequence of SEQ ID No. 161. The scope of the claims includes various unknown and unidentified genes that either encodes or not encodes a polypeptide. No function could be ascribed to the polypeptide sequence of SEQ ID No. 161 or any polypeptide comprising SEQ ID No. 161. A sequence search of SEQ ID No. 161 only provides limited similarity with other polypeptides. The structures of the various unknown and unidentified genes have not been disclosed and there is no known or disclosed correlation between function and structure of the non-described regulatory elements and untranslated regions of the gene. Furthermore, there is no additional disclosure of physical and/or chemical properties. Thus, one skilled in the art at the time of the invention would not be able to envision all the polynucleotide sequences encompassed in the claims.

The claims also encompass various polynucleotides encoding a genus of numerous structural variants of the amino acid sequence of SEQ ID No. 161, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification fails to provide the structural features of the variant proteins. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails

to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the amino acid sequence of SEQ ID No. 161 as disclosed in the present application is insufficient to describe the genus. The nucleotide sequence of SEQ ID No. 160 also is insufficient to describe the claimed polynucleotide sequences.

This limited information is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of the claimed polynucleotide sequences, expression vectors, host cells, and compositions. Thus, it is concluded that the written description requirement is not satisfied for the polynucleotide sequences, such as genes, as claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieve regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the disclosed nucleotide sequence of SEQ ID No. 160, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

9. Claims 1, 3, 4 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide sequence comprising SEQ ID No. 160, does not reasonably provide enablement for any polynucleotide comprising at least 20 contiguous nucleotides of SEQ ID No. 160, any polynucleotide hybridizing to SEQ ID No. 160 under highly stringent condition, any polynucleotide having at least 75% or 90% identity to SEQ ID No. 160, and degenerate variants of SEQ ID No. 160, an expression vector containing said polynucleotide, a host cell containing said vector, a composition comprising said polynucleotide, a method for the treatment of a lung cancer in a patient, and a method for stimulating an immune response in a patient via administering said composition *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to an isolated polynucleotide comprising a sequence of SEQ ID No. 160, complement of SEQ ID No. 160, a sequence consisting of at least 20 contiguous

nucleotides of SEQ ID No. 160, a sequence that hybridizes to SEQ ID No. 160 under highly stringent condition, a sequence having at least 75% or 90% identity to SEQ ID No. 160, degenerate variants of SEQ ID No. 160, an expression vector containing said polynucleotide, a host cell containing said vector, a composition comprising said polynucleotide, a method for the treatment of a lung cancer in a patient, and a method for stimulating an immune response in a patient via administering said composition *in vivo*.

The specification only discloses a polynucleotide sequence of SEQ ID No. 160 and the amino acid sequence (SEQ ID No. 161) encoded by SEQ ID No. 160, recombinant expression of polypeptide encoded by SEQ ID No. 160 (L762P, example 22), and generation of polyclonal antibody specifically recognizes recombinant L762P protein (example 15). Immuno-histochemical analysis using polyclonal antibodies against L762P shows staining in all lung cancer samples tested and some light staining in the bronchiole epithelium (p. 156, second paragraph). The specification further discloses transfection of 343T tumor cells with a retroviral vector comprising the sequence of SEQ ID No. 160 and mice injected intravenously with the L762P-expressing 343T/L762P cells form three time as many lung tumor foci as mice injected with the parent 343T cells (p. 239, example 47). The claims encompass any polynucleotide comprising SEQ ID No. 160, any polynucleotide that has at least 20 contiguous nucleotides of SEQ ID No. 160, hybridizes to SEQ ID No. 160 under highly stringent condition, has at least 75% or 90% identity to SEQ ID No. 160, and degenerate variants of SEQ ID No. 160.

The claims read on adding unknown nucleotide sequence at 5', 3' ends and/or within the nucleotide sequence of SEQ ID No. 160, or deleting or substituting the nucleotide sequence of SEQ ID No. 160. Twenty-five% or ten% difference from the sequence of SEQ ID No. 160

(3951 nucleotides) accounts to about 990 nucleotides and 395 nucleotides, respectively. The resulting polynucleotide sequence differs dramatically from the sequence of SEQ ID No. 160, and the polypeptide encoded by said polynucleotide sequence also could differ dramatically or totally different from the sequence of SEQ ID NO. 161, or the polynucleotide sequence can encode no polypeptide at all. The scope of the claims encompasses various unknown and unidentified genes, cDNAs, or mRNA sequence encoding various structural variants of the amino acid sequence of SEQ ID No. 161. The specification fails to provide the biological function of a polypeptide having the amino acid sequence of SEQ ID No. 161 and fails to provide adequate guidance for how to use said polypeptide having the sequence of SEQ ID No. 161. Since no biological function could be ascribed to SEQ ID No. 161, therefore, no biological function could be ascribed to a polypeptide "comprising" or "consisting of" SEQ ID No. 161.

Further, as discussed above, the claims encompass various polynucleotides encoding numerous structural variants of the amino acid sequence of SEQ ID No. 161. It was known in the art that the amino acid sequence of a polypeptide determines its structural and functional properties (including half-life), and predictability of which amino acid(s) can be removed from or added to a polypeptide's sequence and still result in similar or higher activity or result in stabilization of the protein is extremely complex, and well outside the realm of routine experimentation. Rudinger, 1976 (Peptide Hormones, Parsons, University Park Press, Baltimore, p. 1-7) points out that "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study" (e.g. p. 6). Kaye et al., 1990 (Proc. Natl. Acad. Sci. USA, Vol. 87, pp. 6922-6926) discloses that a single amino acid substitution results in a

retinoblastoma protein defective in phosphorylation and oncoprotein binding (e.g. title). Skolnick et al., 2000 (Trends in Biotech, Vol. 18, p. 34-39) states "Sequence-based methods for function prediction are inadequate because of the multifunctional nature of proteins. However, just knowing the structure of the protein is also insufficient for prediction of multiple functional sites. Structural descriptors for protein functional sites are crucial for unlocking the secrets in both the sequence and structural-genomics projects" (e.g. abstract). Skolnick further states that "Knowing a protein's structure does not necessarily tell you its function" and "Because proteins can have similar folds but different functions, determining the structure of a protein may or may not tell you something about its function" (e.g. p. 36, box 2). Therefore, biological function of a protein was unpredictable from mere amino acid sequence at the time of the invention and even same short stretch of amino acid sequence can show diverse biological functions while surrounded by different background amino acid sequences. It would be unpredictable for the biological function of the numerous variants of SEQ ID No. 161. In view of such, one skilled in the art at the time of the invention would not know how to use the claimed polynucleotides encoding various structural variants of SEQ ID No. 161.

In case the polynucleotide sequence is used as a probe to detect the cancer expression of SEQ ID No. 160 or to stimulate immune response in a host, the specification only discloses the use of the sequence of SEQ ID No. 160. However, the claims encompass adding unknown nucleotide sequence at 5', 3' ends and/or within the nucleotide sequence of SEQ ID No. 160, or deleting or substituting the nucleotide sequence of SEQ ID No. 160. Twenty-five% or ten% difference from the sequence of SEQ ID No. 160 (3951 nucleotides) accounts to about 990 nucleotides and 395 nucleotides, respectively. The resulting polynucleotide sequence differs

dramatically from the sequence of SEQ ID No. 160, and the polypeptide encoded by said polynucleotide sequence also could differ dramatically or totally different from the sequence of SEQ ID NO. 161. Therefore, the claims encompass numerous different polynucleotide sequences that could differ dramatically from the sequence of SEQ ID No. 160, and the encoded polypeptide also could vary dramatically from the sequence of SEQ ID No. 161. The specification fails to provide adequate guidance and evidence for how to use the claimed polynucleotides to detect the expression of SEQ ID No. 160 in vitro or in vivo, and to stimulate immune response as that of SEQ ID NO. 160. Since the claimed polynucleotides may encode a polypeptide that differ dramatically from the sequence of SEQ ID No. 161 or no polypeptide can be encoded by the claimed polynucleotide, it is unclear how to use said polynucleotide to stimulate immune response similar to that of SEQ ID No. 161, or there is no immune response stimulated at all since no polypeptide is expressed. When the claimed polynucleotide is used as a probe for detecting expression of SEQ ID No. 160, it would be unclear how one skilled in the art at the time of the invention would want to use a polynucleotide sequence that differs or differ dramatically from the sequence of SEQ ID No. 160 as a probe to detect the expression of SEQ ID No. 160. It is also unclear whether said polynucleotide sequence would be able to function as a probe to detect the expression of SEQ ID No. 160.

Claim 4 reads on a host cell transfected or transformed with an expression vector in vivo. Claims 4, 12 and 13 read on **gene therapy** for stimulating an immune response in a patient *in vivo* and treating a lung cancer in a patient. No biological function can be ascribed to the amino acid sequence of SEQ ID No. 161 and various proteins encoded by the claimed polynucleotides. The specification fails to provide adequate guidance and evidence for the correlation between the

claimed polynucleotide and a particular lung cancer *in vivo*. Overexpression of a gene in lung cancer cells does not necessarily mean that said gene is associated with said lung cancer. The specification also fails to provide adequate guidance and evidence for how to deliver the claimed polynucleotide sequence under the control of any promoter in any vector and via any administration route to a patient such that sufficient gene product could be produced at the targeted site and whether said expressed gene product can provide therapeutic effects for a particular lung cancer or stimulating a particular immune response in said patient *in vivo*.

The nature of the invention being gene therapy, the state of the prior art was not well developed and was highly unpredictable at the time of filing. While progress has been made in recent years for gene transfer *in vivo*, vector targeting to desired tissues *in vivo* continues to be unpredictable and inefficient as supported by numerous teachings available in the art. For example, Deonarain (1998, Expert Opin. Ther. Pat., Vol. 8, pages 53-69) indicate that one of the biggest problems hampering successful gene therapy is the "ability to target a gene to a significant population of cells and express it at adequate levels for a long enough period of time" (page 53, first paragraph). Deonarain reviews new techniques under experimentation in the art which show promise but states that such techniques are even less efficient than viral gene delivery (see page 65, first paragraph under Conclusion section). Verma (Sept. 1997, Nature, Vol. 389, pages 239-242) reviews vectors known in the art for use in gene therapy and discusses problems associated with each type of vector. The teachings of Verma indicate a resolution to vector targeting has not been achieved in the art (see entire article). Verma also teaches appropriate regulatory elements may improve expression, but it is unpredictable what tissues such regulatory

elements target (page 240, sentence bridging columns 2 and 3). Crystal (1995, Science, Vol. 270, page 404-410) also reviews various vectors known in the art and indicates that "among the design hurdles for all vectors are the need to increase the efficiency of gene transfer, to increase target specificity and to enable the transferred gene to be regulated" (page 409).

Further, Eck et al., 1996 (Goodman & Gilman's The Pharmacological Basis of Therapeutics, McGraw-Hill, New York, p. 77-101) states that the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced are important factors for a successful gene therapy *in vivo* (e.g. bridging pages 81-82). In view of the reasons set forth above, one skilled in the art at the time of the invention would not know how to use the claimed polynucleotides or compositions containing said polynucleotides for treating a lung cancer in a patient or stimulating an immune response and provide therapeutic effects in a patient *in vivo*.

For the reasons set forth above, one skilled in the art at the time of the invention would have to engage in undue experimentation to practice over the full scope of the invention claimed. This is particularly true based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, the level of skill which is high, the amount of experimentation required, and the breadth of the claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 3, 4 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Pauli et al., US Patent No. 6,309,857 ('857).

Claims 1, 3, 4 and 11 are directed to an isolated polynucleotide comprising a sequence of SEQ ID No. 160, complement of SEQ ID No. 160, a sequence consisting of at least 20 contiguous nucleotides of SEQ ID No. 160, a sequence that hybridizes to SEQ ID No. 160 under highly stringent condition, a sequence having at least 75% or 90% identity to SEQ ID No. 160, or degenerate variants of SEQ ID No. 160, an expression vector comprising said polynucleotide, a host cell comprising said expression vector, and a composition comprising said polynucleotide and a physiologically acceptable carrier.

Pauli discloses nucleotide sequence SEQ ID No. 31, which is 99.8% identical to nucleotides 1 to 2938 of SEQ ID No. 160. Pauli also discloses a vector comprising the nucleic acid of SEQ ID No. 31 and a host cell comprising said vector (see claims). The nucleotide sequence of SEQ ID No. 31 would comprise at least 20 contiguous nucleotides of SEQ ID No. 160 and will hybridize to the sequence of SEQ ID No. 160 under highly stringent condition. The

buffer solution containing the nucleic acid or vector is considered a physiologically acceptable carrier. Thus, claims 1, 3, 4 and 11 are anticipated by Pauli.

12. Claims 1, 3 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al., 1997, EST Accession No. AA429919.

Claims 1, 3 and 11 are directed to an isolated polynucleotide comprising a sequence of SEQ ID No. 160, complement of SEQ ID No. 160, a sequence consisting of at least 20 contiguous nucleotides of SEQ ID No. 160, a sequence that hybridizes to SEQ ID No. 160 under highly stringent condition, a sequence having at least 75% or 90% identity to SEQ ID No. 160, or degenerate variants of SEQ ID No. 160, an expression vector comprising said polynucleotide, and a composition comprising said polynucleotide and a physiologically acceptable carrier.

Hillier discloses a human cDNA sequence, EST Accession No. AA429919, which is 100% identical to nucleotides 2408 to 2938 of SEQ ID No. 160. The nucleotide sequence of EST Accession No. AA429919 would comprise at least 20 contiguous nucleotides of SEQ ID No. 160 and will hybridize to the sequence of SEQ ID No. 160 under highly stringent condition. The sequence of EST Accession No. AA429919 is cloned into a plasmid pT7T3D-Pac. The buffer solution containing the nucleic acid or vector is considered a physiologically acceptable carrier. Thus, claims 1, 3 and 11 are anticipated by Hillier.

13. Claims 1, 3 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al., 1998, EST Accession No. AA160879.

Claims 1, 3 and 11 are directed to an isolated polynucleotide comprising a sequence of SEQ ID No. 160, complement of SEQ ID No. 160, a sequence consisting of at least 20 contiguous nucleotides of SEQ ID No. 160, a sequence that hybridizes to SEQ ID No. 160 under highly stringent condition, a sequence having at least 75% or 90% identity to SEQ ID No. 160, or degenerate variants of SEQ ID No. 160, an expression vector comprising said polynucleotide, and a composition comprising said polynucleotide and a physiologically acceptable carrier.

Hillier discloses a human cDNA sequence, EST Accession No. AA160879, which is 100% identical to nucleotides 2799 to 3132 of SEQ ID No. 160. The nucleotide sequence of EST Accession No. AA160879 would comprise at least 20 contiguous nucleotides of SEQ ID No. 160 and will hybridize to the sequence of SEQ ID No. 160 under highly stringent condition. The sequence of EST Accession No. AA160879 is cloned into a plasmid pBluescript SK-. The buffer solution containing the nucleic acid or vector is considered a physiologically acceptable carrier. Thus, claims 1, 3 and 11 are anticipated by Hillier.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER